UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Medtronic Inc., Securities Litigation	Civ. No. 07-4564 (RHK/AJB) **MEMORANDUM OPINION AND ORDER**

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This matter is before the Court on Plaintiffs' Motion to Alter Judgment. For the reasons described below, the Court will deny the Motion.[1]

BACKGROUND

The background of this case is set forth in detail in the Court's March 10, 2009 Order and will not be repeated here. See In re Medtronic, Inc. Sec. Litig., Civ. No. 07-4564, 2009 WL 649688 (D. Minn. Mar. 10, 2009). Plaintiffs filed a Consolidated Class Action Complaint (the "Complaint") accusing Medtronic and three of its high-ranking officers and directors of making material and fraudulent misrepresentations and omissions regarding the efficacy of Medtronic's Sprint Fidelis defibrillator lead (the "Fidelis lead"). The Court concluded that the Complaint did not comply with the strictures of the Private Securities Litigation Reform Act ("the Reform Act"), which

[1] Having reviewed the parties' thorough submissions, the Court has concluded that oral argument would not materially assist its resolution of the issues raised in the Motion.

requires Plaintiffs claiming securities fraud to allege the defendants' fraudulent acts and mental state with particularity. 15 U.S.C. § 78u-4(b). Accordingly, the Complaint was dismissed.

Because the Court dismissed the Complaint with prejudice and without leave to re-plead, Plaintiffs now request relief from the Court's March 10, 2009, Order so that they may amend their Complaint. Plaintiffs assert they are entitled to such relief because (1) they have a right to amend as a matter of course pursuant to Federal Rule of Civil Procedure 15(a)(1)(A), and (2) newly discovered evidence suggests they can replead in conformity with the requirements of the Reform Act, and therefore should be granted relief under Federal Rules of Civil Procedure 59(e) and 60(b).

ANALYSIS

I. Rule 15(a)(1)(A)

Plaintiffs claim that they have a right to amend as a mater of course pursuant to Federal Rule 15(a)(1)(A). (Pls. Mem. at 14-15.) However, the Eighth Circuit has clearly held that the right to amend under Rule 15(a) terminates upon dismissal. Parnes v. Gateway 2000, Inc., 122 F.3d 539, 550 (8th Cir. 1997); Dorn v. State Bank of Stella, 767 F.2d 442, 443 (8th Cir. 1985). Therefore, because the Complaint has been dismissed, Plaintiffs no longer have the right to amend as a matter of course.

II. Rule 59(e)/60(b)

A. Standard of review

Rule 59(e) and Rule 60(b)(2) are "analyzed identically." United States v. Metro. St. Louis Sewer Dist., 440 F.3d 930, 933 n.3 (8th Cir. 2006). Rule 60(b) states in

relevant part that, "[o]n motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons: . . . (2) newly discovered evidence." A Rule 59(e) motion to alter or amend the judgment "serve[s] a limited function of correcting manifest errors of law or fact or to present newly discovered evidence." Innovative Home Health Care, Inc. v. P.T.-O.T. Assocs., 141 F.3d 1284, 1286 (8th Cir. 1998) (internal quotation marks and citation omitted).

Motions to alter or amend the judgment "cannot be used to introduce new evidence, tender new legal theories, or raise arguments which could have been offered or raised prior to entry of judgment." Id. Moreover, the principles of Rules 59(e) and 60(b) are "restrictive" because post-judgment motions for leave to amend are "disfavored." United States *ex rel.* Roop v. Hypoguard USA, Inc., 559 F.3d 818, 823-24 (8th Cir. 2009). Parties are granted relief under Rules 59(e) and 60(b) only in "extraordinary" circumstances. United States v. Young, 806 F.2d 805, 806 (8th Cir. 1987); Dale & Selby Superette & Deli v. United States Dep't of Agric., 838 F. Supp. 1346, 1348 (D. Minn. 1993) (Doty, J.). The "district court has broad discretion in determining whether to grant or deny a motion to alter or amend judgment." Metro. St. Louis, 440 F.3d at 933.

B. The "newly discovered evidence" is insufficient to warrant relief under Rules 59(e)/60(b)

To prevail on a Rule 59(e)/60(b) motion, the movant must show: (1) the evidence was discovered after final judgment; (2) the movant exercised due diligence to discover the evidence prior to final judgment; (3) the evidence is material and not cumulative; and (4) considering the new evidence "would probably produce a different result." Id. (citing

U.S. Xpress Enter., Inc. v. J.B. Hunt Transp., Inc., 320 F.3d 809, 815 (8th Cir. 2003)). This action was dismissed for Plaintiffs' failure to plead with particularity material misrepresentations or omissions in addition to their failure to plead a strong inference of scienter. In re Medtronic, 2009 WL 649688, at *4-18. Plaintiffs assert that "newly discovered evidence" demonstrates that they can properly replead material misrepresentations and scienter. The Court does not agree. Specifically, the Court determines that the newly discovered evidence cannot assist in the pleading of a material misrepresentation or omission, and therefore, Plaintiffs are not entitled to relief from the Court's Order.[2]

Plaintiffs rely on two pieces of new information in asserting that they are now able to properly plead material misrepresentations and omissions. First, new evidence from the FDA demonstrates that Medtronic was aware of three fracture "modes" on the Fidelis lead, but only disclosed the existence of two fracture "modes" in a March 2007 physician letter.[3] (Pls. Mem. at 8-9.) Second, Defendants failed to disclose in this same physician letter that Medtronic was filing an FDA application for design and manufacturing change

[2] The Court expresses no opinion as to whether the newly discovered evidence would assist Plaintiffs in pleading scienter in conformity with the Reform Act, as it is not necessary to the disposition of this Motion.

[3] In their Complaint, Plaintiffs contended that several statements contained in a physician letter sent on March 21, 2007, were materially false and misleading. (Compl. ¶¶ 97-98.) In this letter, Medtronic informed physicians that it had "received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads." (Id. ¶ 97.) Medtronic noted that it had "identified two primary locations" where fractures were occurring. (Id.) However, the company maintained that "current overall Sprint Fidelis performance" was "consistent with other leads." (Id.) Furthermore, Medtronic noted that its investigation suggested that "variables within the implant procedure may contribute significantly to these fractures." (Id.)

approval addressing the undisclosed fracture mode, located on the "DF-1 cable" of the Fidelis lead. (Id.)

Under the Reform Act, a complaint based on material misstatements or omissions must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). An omitted fact is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). Statements or omissions are not material where they "present or conceal such insignificant data that . . . [they] simply would not matter to a reasonable investor." Parnes, 122 F.3d at 547. "Where a reasonable investor could not have been swayed by an alleged misrepresentation, . . . a court may determine, as a matter of law, that the alleged misrepresentation is immaterial." Id. at 546.

Defendants' failure to disclose the existence of the third fracture mode is not a material omission. The March 2007 physician letter addressed the "two primary locations" where fractures had occurred on the Fidelis lead. (Compl. ¶ 97.) Therefore, the omission of a non-primary fracture location cannot render statements in the letter materially false or misleading. Moreover, "[m]edical device and drug manufacturers need not disclose isolated reports of harm suffered by users of their products until those reports provide statistically significant evidence that the ill effects may be caused by -- rather than randomly associated with -- use of the products and are sufficiently serious and frequent to affect future earnings." In re Medtronic, 2009 WL 649688, at *5 (quoting

In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998)) (internal quotation marks and alterations omitted). Plaintiffs do not argue that the fractures occurring on the "DF-1 cable" were statistically significant. Therefore, the existence of this fracture mode, in and of itself, cannot constitute a material omission.

Additionally, the existence of a third fracture mode is not new evidence, as this mode was disclosed when the Fidelis lead was pulled from the market. Specifically, Medtronic noted in a second physician letter released on October 15, 2007, that there were four fracture modes on the Fidelis lead, but that two "primary locations . . . [accounted] for 90% of the chronic fractures." (Strauss Decl. in Opp'n to Motion to Dismiss Ex. F.) Thus, Plaintiffs were aware of these additional fracture modes when they filed this action. Accordingly, the third mode is not "newly discovered evidence" and will not be considered. Innovative, 141 F.3d at 1286.

Nor is Defendants' failure to disclose the FDA application a material omission. In the March 2007 physician letter, Medtronic disclosed to physicians that fractures were occurring at "two primary locations" of the Fidelis lead. (Compl. ¶ 97.) The letter went on to explain that "[a]t this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures." (Id.) The Court agrees that if Medtronic had submitted an FDA application for design and manufacturing changes to address the fracturing at these "primary locations," this statement suggesting that implant procedures were a cause of the fracturing might well be materially misleading without the disclosure of the FDA application. See Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp., 523 F.3d 75, 87 (1st Cir. 2008). However, the DF-1

cable fractures were not the subject of the March 2007 physician letter because they were not the "primary" fractures causing concern. Defendants did not have an obligation to disclose the statistically insignificant fractures occurring on the DF-1 cable, nor did they have an obligation to disclose the response to this fracturing. While it is true that "once corporate officers undertake to make statements, they are obligated to speak truthfully," In re Par Pharm., Inc. Sec. Litig., 733 F. Supp. 668, 675 (S.D.N.Y. 1990), Medtronic did not choose to speak about non-primary fractures.

Moreover, Medtronic's FDA application is not an "other indication" of materiality. "[I]nformation may become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse . . . events is legitimate and serious enough to threaten . . . sales." In re Elan Corp. Sec. Litig., 543 F. Supp. 2d 187, 210 (S.D.N.Y. 2008). Defendants' response to the DF-1 cable fracturing does not indicate their belief as to the seriousness of the threat posed by the primary fracture modes. The fact that Medtronic sought a design and manufacturing change for the DF-1 cable does not indicate that Medtronic believed that the risk posed by Fidelis lead fracturing was "legitimate and serious enough to threaten . . . sales" at the time the physician letter was distributed. Id.

The Court noted in its March 2009 Order that there were "no facts showing that the FDA application was made in response to a fracturing concern." In re Medtronic, 2009 WL 649688, at *8. Plaintiffs assert that the newly discovered evidence demonstrates that the FDA application was made in response to a fracturing concern and they should be allowed to plead it. (Reply Mem. at 7.) However, the new evidence

makes clear that the FDA application was not made in response to the specific fracturing concern discussed in the March 2007 physician letter. Therefore, the failure to disclose the FDA application does not render the physician letter materially false or misleading.

In sum, Plaintiffs have not demonstrated that considering the new evidence "would probably produce a different result." Metro. St. Louis, 440 F.3d at 933. Plaintiffs' newly discovered evidence cannot alter the Court's initial determination that they are unable to plead a material misrepresentation or omission. Therefore, an amendment of their Complaint would be futile and relief from the Court's Order is not warranted.

CONCLUSION

Based on the foregoing, and all the files, records and proceedings herein, **IT IS ORDERED** that Plaintiffs' Motion to Alter Judgment (Doc. No. 87) is **DENIED**.

Dated: May 29, 2009

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge